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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/996,658	11/29/2001	James M. Coull	027232-000910US	5256

52059 7590 05/20/2010

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EXAMINER	
SISSON, BRADLEY L	

ART UNIT	PAPER NUMBER
1634	

MAIL DATE	DELIVERY MODE
05/20/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/996,658	COULL ET AL.	
	Examiner	Art Unit	
	Bradley L. Sisson	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 May 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4,5,7,8,11,15-18,21,22,24-26,29-31,35,38,39,41-43 and 46-48* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4,5,7,8,11,15-18,21,22,24-26,29-31,35,38,39,41-43 and 46-48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 November 2001* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 03 May 2010 has been entered.

Drawings

2. New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because:

a. Figure(s) 1A and 1B is/are not properly labeled. See 37 CFR 1.84(u)(1).

b. The lettering is not of proper size, uniform density, and well-defined in Figure(s) 1A and 1B. See 37 CFR 1.84 (l) and (p)(1) – (5). ("Numbers, letters, and reference characters must measure at least .32 cm (1/8 inch) in height.")

c. The images/photographs are not of sufficient quality so that all details in the photographs are reproducible in printed patent- FIG(s) 1A and 1B . See 37 CFR 1.84(b)(1).

3. Applicant is advised to employ the services of a competent patent draftsperson outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The

corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

INFORMATION ON HOW TO EFFECT DRAWING CHANGES

Replacement Drawing Sheets

Drawing changes must be made by presenting replacement sheets which incorporate the desired changes and which comply with 37 CFR 1.84. An explanation of the changes made must be presented either in the drawing amendments section, or remarks, section of the amendment paper. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). A replacement sheet must include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of the amended drawing(s) must not be labeled as "amended." If the changes to the drawing figure(s) are not accepted by the examiner, applicant will be notified of any required corrective action in the next Office action. No further drawing submission will be required, unless applicant is notified.

Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and within the top margin.

Annotated Drawing Sheets

A marked-up copy of any amended drawing figure, including annotations indicating the changes made, is required by the examiner. The annotated drawing sheet(s) must be clearly labeled as "Annotated Sheet" and must be presented in the amendment or remarks section that explains the change(s) to the drawings.

Timing of Corrections

Applicant is required to submit acceptable corrected drawings within the time period set in the Office action. See 37 CFR 1.85(a). Failure to take corrective action within the set period will result in ABANDONMENT of the application.

Specification

4. The specification contains numerous bibliographic citations, and states at page 8, lines 18-19, and at page 11, lines 12-13, that "all of which are herein incorporated by reference." The specification also states at page 13, line 20, and page 14, line 26, that the documents are "herein incorporated by reference." As set forth in *Advanced Display Systems Inc. v. Kent State University* (Fed. Cir. 2000) 54 USPQ2d at 1679:

> Incorporation by reference provides a method for integrating material from various documents into a host document--a patent or printed publication in an anticipation determination--by citing such material in a manner that makes it clear that the material is effectively part of the host document as if it were explicitly contained therein. *See General Elec. Co. v. Brenner*, 407 F.2d 1258, 1261-62, 159 USPQ 335, 337 (D.C. Cir. 1968); *In re Lund*, 376 F.2d 982, 989, 153 USPQ 625, 631 (CCPA 1967). **To incorporate material by reference, the host document must identify with detailed particularity what specific material it incorporates and clearly indicate where that material is found in the various documents.** *See In re Seversky*, 474 F.2d 671, 674, 177 USPQ 144, 146 (CCPA 1973) (providing that incorporation by reference requires a statement "clearly identifying the subject matter which is incorporated and where it is to be found"); *In re Saunders*, 444 F.2d 599, 602-02, 170 USPQ 213, 216-17 (CPA 1971) (reasoning that a rejection or anticipation is appropriate only if one reference "expressly incorporates a particular part" of another reference); *National Latex Prods. Co. v. Sun Rubber Co.*, 274 F.2d 224, 230, 123 USPQ 279, 283 (6th Cir. 1959) (requiring a specific reference to material in an earlier application in order to have that material considered a part of a later application); *cf. Lund*, 376 F.2d at 989, 13 USPQ at 631 (holding that a one sentence reference to an abandoned application is not sufficient to incorporate from the abandoned application into a new application). (Emphasis added.)

Attention is also directed to MPEP 201.06(c), which, in pertinent part, is reproduced below:

> The inclusion of this incorporation by reference statement will permit an applicant to amend the continuation or divisional application to include subject matter from the prior application(s), without the need for a petition provided the continuation or divisional application is entitled to a filing date notwithstanding the incorporation by reference. For applications filed prior to September 21, 2004, the incorporation by reference statement may appear in the transmittal letter or in the specification. Note that for applications filed prior to September 21, 2004, if applicants used a former version of the transmittal letter form provided by the USPTO, the incorporation by reference statement could only be relied upon to add inadvertently omitted material to the continuation or divisional application.

> For applications filed on or after September 21, 2004, a claim under 35 U.S.C. 120 and 37 CFR 1.78 for benefit of a prior-filed nonprovisional application or international application designating the U.S. that was present on the filing date of the continuation or divisional application is considered an incorporation by reference of the prior-filed application as to inadvertently omitted material, subject to the conditions and requirements of 37 CFR 1.57(a). (Emphasis added)

Accordingly, the cited documents are not considered to have been incorporated by reference and as such, have not been considered with any effect towards their fulfilling, either in part or in whole, the enablement, written description, or best mode requirements of 35 USC 112, first paragraph.

Response to argument

5. At pages 15-16 of the response received 20 September 2005, applicant's representative asserts that the objection to the specification should be withdrawn, citing that the citing of Advanced Display Systems Inc. is "misplaced." This traversal has not been found persuasive. As set forth in *Ex parte Raible*, 8 USPQ2d 1709, (BPAI, 1998)

> The examiner is of the opinion that the general incorporation by reference of the Bentley disclosure in appellant's specification is insufficient to support the specific disputed limitations of the present claims in the manner required by section 112 of the statute. We agree.
> ***
> We believe that the doctrine of incorporation by reference is of no avail to appellant in this regard since there is no specific indication in the instant specification of the particular features disclosed by Bentley which correspond to those intended for use in the here-claimed device; nor does the specification identify the specific portions of the patent which appellant may have intended to rely upon .to supplement his disclosure. The purpose of incorporation by reference in an application of matter elsewhere written down is for economy, amplification, or clarity of exposition, by means of an incorporating statement clearly identifying the subject matter which is incorporated and where it is to be found. *In re de Seversky*, 474 F.2d 671,177 USPQ 144, (CCPA 1973).
> ***
> For the sake of completeness, we take notice of the decision in *In re Voss* , 557 F.2d 812, 194 USPQ 267 (CCPA 1977). We recognize that *Voss* , like the present case, involved an attempt to rely upon the incorporation by reference of a U.S. patent for descriptive support of a particular limitation in the claims. However, the decision in *Voss*

> is not dispositive of the issue before us, and is distinguishable on its facts for the following reasons:
> (1) In *Voss* , the incorporating statement particularly referred to the aspect of the patent which was being relied upon, i.e., "for a general discussion of glass-ceramic materials and their production". Here, as previously indicated, there is no reference in the incorporating statement to any specific portion or aspect of the Bentley disclosure. Actually, the incorporating statement involved here more broadly refers to several patents with no specific indication of the relevance of each to the claimed invention.

The case at hand is analogous to that of *Raible* inn that applicant seeks to incorporate by reference "broadly refers to several patents [and non-patent documents] with no specific indication of the relevance of each to the claimed invention." Accordingly, the cited documents are not considered to have been properly incorporated by reference and as such, have not been considered with any effect towards their fulfilling, either in part or in whole, the enablement, written description, or best mode requirements of 35 USC 112, first paragraph. While an applicant may utilize bibliographic citations in an application's specification so to establish the level of skill and/or state of the art at the time of filing, such documents, as is here, have not been properly incorporated so as to be useful in satisfying either the written description or best mode requirements of 35 USC 112, first paragraph. Additionally, to the extent that the documents contains essential subject matter required for the enablement of the claims, and said document is not an issued US patent, said documents cannot be relied upon for satisfaction of the enablement requirement of 35 USC 112, first paragraph.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1, 4, 5, 7, 8, 11, 15-18, 21,22, 24-26, 29-31, 35, 38, 39, 41-43, and 46-48 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

8. Claims 1, 18, and 35 are the only independent claims pending and under consideration. Claim 1 is exemplary, and for convenience, is reproduced below.

1. (Previously presented): A method for determining the presence of a microbial organism of interest in a sample from another organism or organisms, said method comprising:

treating the sample, or a portion thereof, with at least one detectable molecular probe wherein the molecular probe or probes are peptide nucleic acid and are selected such that either:

(i) a target sequence of both the microbial organism of interest and the other organism or organisms reacts with the molecular probe in a way that produces detectable microbial organisms of interest and a detectable other organism or organisms; or

(ii) a target sequence of only the microbial organism of interest reacts with the molecular probe in a way that produces only detectable organisms of interest; and

contacting the sample, or a portion thereof, with a solid carrier to which has been immobilized an antibody such that if (i) applies then the antibody is chosen to be reactive only with the detectable microbial organism of interest but not reactive with the detectable other organism or organisms; but if (ii) applies then the antibody is chosen to be generally reactive with the detectable microbial organism of interest but also may be reactive with the other organism or organisms; and

determining the presence or number of detectable microbial organisms immobilized to the solid carrier.

9. Attention is directed to MPEP 904.01.

> The breadth of the claims in the application should always be carefully noted; that is, the examiner should be fully aware of what the claims do not call for, as well as what they do require. During patent examination, the claims are given the broadest reasonable interpretation consistent with the specification. See In re Morris, 127 F.3d 1048, 44 USPQ2d 1023 (Fed. Cir. 1997). See MPEP § 2111 - § 2116.01 for case law pertinent to claim analysis.

10. It is noted with particularity that narrowing limitations found in the specification cannot be inferred in the claims where the elements not set forth in the claims are linchpin of patentability. *In re Philips Industries v. State Stove & Mfg. Co, Inc.*, 186 USPQ 458 (CA6 1975). While the claims are to be interpreted in light of the specification, it does not follow that limitations from the specification may be read into the claims. On the contrary, claims must be interpreted as broadly as their terms reasonably allow. See *Ex parte Oetiker*, 23 USPQ2d 1641 (BPAI, 1992).

11. As set forth in *In re Alonso* 88 USPQ2d 1849 (Fed. Cir. 2008), at 1851:

> The written description requirement of 35 U.S.C. § 112, ¶ 1, is straightforward: "The specification shall contain a written description of the invention …." To satisfy this requirement, the specification must describe the invention in sufficient detail so "that one skilled in the art can clearly conclude that the inventor invented the claimed invention as of the filing date sought." *Lockwood v. Am. Airlines, Inc.*, 107 F.3d 1565, 1572 [41 USPQ2d 1961] (Fed. Cir. 1997); *see also LizardTech, Inc. v. Earth Res. Mapping, Inc.*, 424 F.3d 1336, 1345 [76 USPQ2d 1724] (Fed. Cir. 2005); *Eiselstein v. Frank*, 52 F.3d 1035, 1039 [34 USPQ2d 1467] (Fed. Cir. 1995).

Alonso at 1852:

> A genus can be described by disclosing: (1) a representative number of species in that genus; or (2) its "relevant identifying characteristics," such as "complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics." *Enzo*, 323 F.3d at 964.

12. In applying the test as set forth in *Alonso*, it is noted that applicant is claiming a generic method of 'determining the presence of a microbial organism of interest." The microbe of interest is without limit. As set forth at page 19 of the disclosure:

> As used herein, the organism of interest is a microorganism, tissue or microscopic sized cell. The organism of interest may be a cell, bacteria, virus, yeast, fungi, other unicellular organism or a multicellular organism. Thus, there are no limitations in the organism of interest except that it be microscopic in size.
> The organism of interest is generally selected to be an organism characterized by domain, kingdom, group, class, genus, species, taxon, subclass, subspecies, serotype, strain or by any other recognized means of characterization of the organism of interest. Optionally, but not necessarily, the organism of interest will be chosen such that it is to be distinguished from a closely related organism or organisms wherein an antibody or probe based assay, alone, is not adequate to properly characterize the organism of interest from the organism or organisms to be distinguished.

13. The claimed method has also been construed as encompassing the simultaneous determination of the "presence or number" of multiple microbial organisms of interest. In support of this position, attention is directed to page 29 of the specification, which states in part:

> It should be noted, that the number of different organisms of interest that can be determined is limited only by the number of different independently detectable molecular probes that can be prepared and that five organisms per sample is not intended to be a limit on the method. Furthermore, it is evident that 100 different types of coded beaded supports is not intended to be a limit on the method.

14. Applicant, at page 36 of the disclosure states:

> Two types of coded beads were received from LUMINEX, one coated with Salmonella-specific antibody (OEM Concepts, Toms River, NJ; the "Salmonella beads") and one with Listeria-specific antibody (OEM Concepts, Toms River, NJ; the "Listeria beads").

15. A review of the disclosure also finds that applicant has disclosed but a single PNA sequence. The disclosure clearly indicates that the one and only example did not function as intended, and that applicant presents forward-looking statements as to their future plans to unravel "why the selected specificity was not achieved." Such explicit statements do not

reasonably suggest that applicant had possession of the generic reagents needed to practice the full scope of the claimed invention. Indeed, even under conditions selected by applicant, the desired results were not obtained when but two microorganisms were selected. Clearly, the example provided does not describe how one is to accurately and reproducibly determine the number of microbes present, much less in excess of 100 different microbial organisms of interest.

16. At page 17 of the disclosure applicant recognizes that one will need to "harmonize" conditions for both antibody binding and PNA binding/hybridization. Rather than describe suitable conditions, applicant is seemingly looking to the future, and what the public will be able to resolve. As stated therein:

> When employing the methods of this invention or in the production of the compositions of this invention, it maybe important to harmonize the hybridization conditions with the antibody binding conditions because the staining of the organisms is performed simultaneously with, or subsequent to, an antibody binding event. Because optimization of the same variables (pH, salt concentration etc.) is involved, aided by no more than routine experimentation, those of skill in the art will easily be able to harmonize the antibody binding conditions and suitable hybridization conditions for performing an assay. It should however be noted that the use of non-nucleic acid, and preferably PNA probes, is preferred when harmonization of the hybridization and antibody binding conditions is required because PNA probe bind more tightly under conditions of physiological salt, conditions under which antibodies are more likely to operate most efficiently. (Emphasis added)

For purposes of examination, the claimed method has been construed as encompassing harmonization of conditions between PNA probes and antibodies, as both are required in the present claims. Further, the claimed method has been construed as encompassing both simultaneous and sequential binding of PNA probe and antibody. Again, the specification does not set forth an adequate written description of the conditions to be employed.

17. The specification extols the virtues of using blocking probes, however, the claimed method has been construed as not requiring any blocking probe, and yet binding of probe to non-target nucleic acid sequence can reasonably be expected to occur and result in false signals. The specification has not been found to describe how signals resulting from probe binding to target vs. non-target nucleic acids are to be correctly and reproducibly detected when the same signal from binding of probe to non-target nucleic acids is occurring.

18. In view of the limited showing, and the fact that applicant admits that "the selected specificity was not achieved," the disclosure has not been found to satisfy either prong of the written description test (disclose either "(1) a representative number of species in that genus; or (2) its 'relevant identifying characteristics,' such as 'complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics'").

19. At pages 2-3 of the response of 10 January 2005, applicant asserts:

> There is a strong presumption that an adequate written description of the claimed invention is present when the application is filed." M.P.E.P. § 2163 (I)(A). The examiner, therefore, must have a reasonable basis to challenge the adequacy of the written description". M.P.E.P. § 2163.04 In rejecting a claim, the examiner must set forth express findings of fact which support the lack of written description conclusion..." M.P.E.P. § 2163.04(I).
> "The analysis of whether the specification complies with the written description requirement calls for the examiner to compare the scope of the claim with the scope of the description to determine whether applicant has demonstrated possession of the claimed invention. Such a review is conducted from the standpoint of one of skill in the art at the time the application was filed .... " M.P.E.P. § 2163(II)(A)(2) "Information which is well known in the art need not be described in detail in the specification." *Id.*

20. As presented above, the scope of the claims has been determined and compared with the description provided. Further, the level of disclosure was applied to the two-prong test set forth in *Alonso*. A showing of fact has been made, and it has been determined that the level of

disclosure is not adequate to reasonably conclude that applicant was in possession, at the time of filing, of the generic method contemplated/claimed.

21. While an applicant is note required to teach each and every possible embodiment encompassed by the claims, applicant is still required to fully describe the entire scope of the invention so as to reasonably suggest that applicant had possession of the invention. Agreement is reached that an applicant is not required to disclose that which is well known in the art. However, such does not permit applicant to assert that all aspects of the invention are well known. The situation at hand is analogous to that in *Genentech v. Novo Nordisk A/S* (Fed. Cir. 1997) 42 USPQ2d 1001. As set forth in the decision of the Court:

> "It is true . . . that a specification need not disclose what is well known in the art. *See, e.g., Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1385, 231 USPQ 81, 94 (Fed. Cir. 1986). However, that general, oft-repeated statement is merely a rule of supplementation, not a substitute for a basic enabling disclosure. It means that the omission of minor details does not cause a specification to fail to meet the enablement requirement. However, when there is no disclosure of any specific starting material or any of the conditions under which a process can be carried out, undue experimentation is required; there is a failure to meet the enablement requirement that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art. It is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement. This specification provides only a starting point, a direction for further research. (Emphasis added)

22. In the present case applicant has disclosed but one nucleic acid probe and has indicated that antibody-labeled beads were secured through a commercial vendor. The disclosure clearly indicates that the one and only example did not function as intended, and that applicant presents forward-looking statements as to their future plans to unravel "why the selected specificity was not achieved." Further, applicant is clearly relying upon the public to determine just what conditions are required in order for harmonization between antibody and PNA probe binding.

Such explicit statements do not reasonably suggest that applicant had possession of the generic reagents needed to practice the full scope of the claimed invention, nor does the disclosure reasonably suggest that applicant was in possession of the conditions required for the essential reagents to work in an accurate and reproducible manner.

23. While applicant has indicated that two different colors were employed, the aspect of being able to accurately and reproducibly quantify 100 or more different microbes in a simultaneous manner has not been adequately described. It is noted that the claimed method does not recite use of any device to achieve the requisite level of detection, and the method does not require one utilize any control. Further, the specification has not been found to provide a description of any controls, be they immunologic or PNAs.

24. It appears that applicant is attempting to satisfy the written description requirement of 35 USC 112, first paragraph, through obviousness. Obviousness, however, cannot be relied upon for satisfaction of the written description requirement. In support of this position, attention is directed to the decision in *University of California v. Eli Lilly and Co.* (Fed. Cir. 1997) 43 USPQ2d at 1405, citing *Lockwood v. American Airlines Inc.* (Fed. Cir. 1997) 41 USPQ2d at 1966:

> Recently, we held that a description which renders obvious a claimed invention is not sufficient to satisfy the written description requirement of that invention.

25. At page 17, bridging to page 18, of the response of 20 September 2005, applicant directs attention to where definitions of terms are provided, seemingly implying that the definitions provide an adequate written description of the essential elements. For convenience the definitions of "probe and "detectable molecular probe" are reproduced below.

f. As used herein, the term "probe" or "molecular probe" means a nucleic acid or non-nucleic acid polymer (e.g. a DNA, RNA, PNA, nucleic acid analogs, nucleic acid mimics, chimera or linked polymer) having a probing nucleobase sequence that is designed to sequence specifically hybridize to a target sequence of a target molecule of an organism of interest.

g. As used herein, a "detectable molecular probe" is a probe or molecular probe that is detectable by instrument or method. For the avoidance of doubt, a "detectable molecular probe" need not be directly labeled with a detectable moiety (See: the subsection entitled: "Unlabeled Molecular Probes", below for a discussion of determining unlabeled molecular probes).

The aspect of describing a "probe" as being DNA, RNA, PNA, etc., of that it "specifically hybridizes to a target sequence of a target nucleic acid" is not an adequate description of the members of that genus. In support of this position, attention is directed to the decision of *Fiers v. Sugano* 25 USPQ2d 1604-5 (CAFC, January 1993) wherein is stated:

> We also reject *Fiers* argument that the existence of a workable method for preparing a DNA establishes conception of that material. Our statement in *Amgen* that conception may occur, *inter alia*, when one is able to define a chemical by its method of preparation requires that the DNA be claimed by its method of preparation. We recognize that, in addition to being claimable by structure or physical properties, a chemical material can be claimed by means of a process. A product-by-process claim normally is an after-the-fact definition, used after one has obtained a material by a particular process. Before reduction to practice, conception only of a process for making a substance, without a conception of a structural or equivalent definition of that substance, can at most constitute conception of the substance claimed as a process. Conception of a substance claimed *per se* without reference to a process requires conception of its structure, name, formula, or definitive chemical or physical properties. . .
> * * * *
> The difficulty that would arise if we were to hold that a conception occurs when one has only an idea of a compound, defining it by its hoped-for function, is that would-be inventors would file patent applications before they had made their inventions and before they could describe them. That is not consistent with the statute or the policy behind the statute, which is to promote disclosure of inventions.

Attention is also directed to the decision of *University of California v. Eli Lilly and Co.* (CA FC, July 1997) 43 USPQ2d 1398 wherein is stated:

> In claims involving chemical materials, generic formulas usually indicate with specificity what the generic claims encompass. One skilled in the art can distinguish such a formula from others and can identify many of the species that the claims encompass. Accordingly, such a formula is normally an adequate written description of the claimed genus. In claims to genetic material, however, a generic statement such as "vertebrate insulin cDNA" or "mammalian cDNA," without more, is not an adequate written description of the genus because it does not distinguish the claimed genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is See Fiers, 984 F.2d at 1169-71, 25 USPQ2d at 1605-06 (discussing Amgen). It is only a definition of a useful result rather than a definition of what it achieves as a result. Many such genes may achieve that result. The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. *See In re Wilder*, 736 F.2d 1516, 222 USPQ 369, 372-373 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material.
>
> Thus, as we have previously held, a cDNA is not defined or described by the mere name "cDNA," even if accompanied by the name of the protein that it encodes, but requires a kind of specificity usually achieved by means of the recitation of the sequence of nucleotides that make up the cDNA. See Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606.

26. In accordance with claims 1, 18, and 35, "the molecular probe or probes are peptide nucleic acid and are selected such that either:

> (i) a target sequence of both the microbial organism of interest and the other organism or organisms reacts with the molecular probe in a way that produces detectable microbial organisms of interest and a detectable other organism or organisms; or
> (ii) a target sequence of only the microbial organism of interest reacts with the molecular probe in a way that produces only detectable organisms of interest."

The claims' language fails to take into consideration that while a probe may well be specific (e.g., perfectly complementary for a sequence found in only the organism of interest) for a given target under certain conditions, the same probe can bind to other, less complementary sequences, when less stringent conditions are employed. Indeed, even the same probe can be specific or not specific, depending upon conditions used. The claims do not recite/require any hybridization conditions and the specification does not teach that certain conditions, e.g., specific levels of stringency, are required to achieve the level of specificity required. In accordance with the claims, seemingly the nucleotide sequence of the PNA probe alone dictates whether or not the probe(s) will produce one type of result or another. Applicant has not disclosed/described the genus of probes, or for that mater, even a species of probe, "that produces only detectable organisms of interest," regardless of conditions used. Such non-disclosure on the part of applicant of such essential materials presents sufficient reason to doubt that applicant had possession of the full scope of the invention at the time of filing.

Claim Rejections - 35 USC § 103

27. The rejection of claims under 35 USC 103(a) has been withdrawn.

Conclusion

28. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US Patent 56,334,501 (Adams et al.) discloses using probes that are either universal, specific, or both, where one or the other is bound to a support, and a target nucleic acid is detected via hybridization (see column 8).

29. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (571) 272-0751. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave T. Nguyen can be reached on (571) 272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

31. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bradley L. Sisson/
Primary Examiner, Art Unit 1634